DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-002

May 15, 2015

Suzhou Minhua Medical Apparatus Supplies Co., Ltd.
c/o Rhonda Alexander, Senior Regulatory Specialist
Registrar Corp.
Medical Device Division
144 Research Drive
Hampton, Virginia 23666

Re: K143728
Trade/Device Name: Minhua Disposable Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: March 24, 2015
Received: March 25, 2015

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Minhua Disposable Blood Pressure Cuff

Indications for Use *(Describe)*
The Minhua Disposable Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure monitoring systems for determination of a person's blood pressure. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY (21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

The assigned 510(k) number is:_____

Premarket Notification [510(k)] Summary

A. General Information

Submitter's Name:	Suzhou Minhua Medical Apparatus Supplies Co., LTD
Address:	You Yi Industrial park, Songlin Town, WuJiang ,CHINA 215222
Telephone:	+86 21 59840221-8003
Fax Number:	+86 21 59841086
Contact Person:	Ji Dong Yang, Vice General Manager
E-mail:	QD@minhuayiliao.com
Date Prepared:	September. 03, 2014

B. Device

Trade Name:	Minhua Disposable Blood Pressure Cuff
Common Name:	Blood Pressure Cuff
Product Code:	DXQ
Class:	Class 2
Regulation Number:	21 CFR 870.1120
Review Panel:	Cardiovascular

C. Identification of Legally Marketed Predicate Device

Name:	Medline Disposable Blood pressure cuffs
Manufacture:	Medline Industries, Inc.
K Number:	K071244
Date Cleared:	March 5, 2008

D. Description of the Device

The device comprises tubing attached to an inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb, secured by hook and loop closure, and used to measure the patient's blood pressure. The device tubing is connected to a non-invasive blood pressure measurement system.

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E. Intended Use

Indirect measurement of blood pressure.

F .Indications for use

The Minhua Disposable Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure monitoring systems for determination of a person's blood pressure. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

G. Various size

Model	Cuff Size	Arm Range	Bladder Range
002DC01NJT1	100x26mm	30-60mm	68x26mm
002DC01NJT2	100x26mm	30-60mm	
002DC02NJT1	119x31mm	40-80mm	76 x 31mm
002DC02NJT2	119x31mm	40-80mm	
002DC03NJT1	146x41mm	60-110mm	96 x 41mm
002DC03NJT2	146x41mm	60-110mm	
002DC04NJT1	181x48mm	70-130mm	123 x 48mm
002DC04NJT2	181x48mm	70-130mm	
002DC05NJT1	191x56mm	80-150mm	132 x 56mm
002DC05NJT2	191x56mm	80-150mm	
002DC06NJT1	195x55mm	80-140mm	85 x 55mm
002DC06NJT2	195x55mm	80-140mm	
002DC07NJT1	274x83mm	130-200mm	135 x 83mm
002DC07NJT2	274x83mm	130-200mm	
002DC09NJT1	335x107mm	180-260mm	185 x 107mm
002DC09NJT2	335x107mm	180-260mm	
002DC11NJT1	524x143mm	260-350mm	265 x 143mm
002DC11NJT2	524x143mm	260-350mm	
002DC13NJT1	605x174mm	320-420mm	325 x 174mm
002DC13NJT2	605x174mm	320-420mm	
002DC15NJT1	745x198mm	420-500mm	425 x 198mm
002DC15NJT2	745x198mm	420-500mm	

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H. Comparison to the Predicate Device

Features	**Su Zhou Minhua Medical Apparatus Supplies Co., Ltd**		**Medline Industries, Inc.**	
Intended use	Indirect measurement of blood pressure		Indirect measurement of blood pressure	
Patient Populations	Adults/Pediatrics		Adults/Pediatrics	
Tube Configuration	One or two tube		One or two tube	
Sterility	Not supplied sterile		Not supplied sterile	
Pressure limits	0-300mmHg		0-300mmHg	
Biocompatibility	Comply with ISO **10993** biocompatibility evaluation		Comply with ISO **10993** biocompatibility evaluation	
cuff	Non-woven fabric, Nontoxic		Non-woven fabric, Nontoxic	
Tube port	PVC:stable;corrosion resistance;heat-resistance		PVC:stable;corrosion resistance;heat-resistance	
connector	PVC:stable;corrosion resistance;heat-resistance		PVC:stable;corrosion resistance;heat-resistance	
Hook & loop fastener	Non-woven fabric+Nylon brushed fabric :stable, corrosion resistance; heat-resistance;		Non-woven fabric+Nylon brushed fabric	
	Conform to AHA bladder sizes		**Conform to AHA bladder sizes**	
	Recommendations		Recommendations	
	Neonatal 1	002DC01NJT1 100x26mm (3-6cm)	Neonatal 1	MDS 9741 100x26mm (3-6cm)
		002DC01NJT2 100x26mm (3-6cm)		MDS 9751 100x26mm (3-6cm)
	Neonatal 2	002DC02NJT1 119x31mm (4-8cm)	Neonatal 2	MDS 9742 119x31mm (4-8cm)
		002DC02NJT2 119x31mm (4-8cm)		MDS 9752 119x31mm (4-8cm)
	Neonatal 3	002DC03NJT1 146x41mm (6-11cm)	Neonatal 3	MDS 9743 146x41mm (6-11cm)
		002DC03NJT21 146x41mm (6-11cm)		MDS 9753 146x41mm (6-11cm)
	Neonatal 4	002DC04NJT1 181x48mm (7-13cm)	Neonatal 4	MDS 9744 181x48mm (7-13cm)
		002DC04NJT2 181x48mm (7-13cm)		MDS 9754 181x48mm (7-13cm)
	Neonatal 5	002DC05NJT1 191x56mm (8-15cm)	Neonatal 5	MDS 9745 191x56mm (8-15cm)
		002DC05NJT2 191x56mm (8-15cm)		MDS 9755 191x56mm (8-15cm)
	Infant	002DC06NJT1 195x55mm (8-14 cm)	Infant	MDS 9710 195x55mm (8-14cm)
		002DC06NJT2 195x55mm (8-14 cm)		MDS 9720 195x55mm (8-14cm)

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Size	Child	002DC07NJT1 274X83mm (13-20cm)	Child	MDS 9711 274X83mm (13-20cm)
		002DC07NJT2 274X83mm (13-20cm)		MDS 9721 274X83mm (13-20cm)
	Small adult	002DC09NJT1 335x107mm (18-26cm)	Small adult	MDS 9712 335x107mm (18-26cm)
		002DC09NJT2 335x107mm (18-26cm)		MDS 9722 335x107mm (18-26cm)
	Adult	002DC11NJT1 524X143mm (26-35cm)	Adult	MDS 9713 524X143mm (26-35cm)
		002DC11NJT2 524X143mm (26-35cm)		MDS 9723 524X143mm (26-35cm)
	Big adult	002DC13NJT1 605x174mm (32-42cm)	Big adult	MDS 9714 605x174mm (32-42cm)
		002DC13NJT2 605x174mm (32-42cm)		MDS 9724 605x174mm (32-42cm)
	Thigh	002DC15NJT1 745x198mm (42-50cm)	Thigh	MDS 9715 745x198mm (42-50cm)
		002DC15NJT2 745x198mm (42-50cm)		MDS 9725 745x198mm (42-50cm)

The Minjua Disposable Blood Pressure Cuff has the same intended use, basic construction, and technology specification as the predicated device. Both devices are wrapped the patient's arm or leg and secured by a hook and loop fastener commonly called Velcro. Both devices are available in the same size and range and are intended for the same patient populations. The materials of both devices are all conformed to ISO 10993. As with the predicate, we provide extended sizes of the cuffs in order to accommodate special groups, such as overweight subjects. Based on the performance testing in this submission, the slight difference between these blood pressure cuffs does not raise any safety or effectiveness issue.

I. Summary of testing

The Minhua Disposable Blood Pressure Cuff has been tested according to the following standards:
*ANSI/AAMI SP 10, Manual, electronic or automated sphygmomanometers, 2002+A1:2003+A2:2006+(R)2008

*ISO 10993-1, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, 2009

*ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for In Vitro cytotoxicity, 2009

*ISO 10993-10, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin

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sensitization :2010

J. Conclusion of Substantial Equivalence

Based on the comparison of intended use, design, materials and performance, we conclude that the new device is substantially equivalent to the predicate. The differences between the devices do not raise new questions of safety and effectiveness.